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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,839	06/15/2000	James Anthony	2629-4017	3097
27123	7590	09/22/2004	EXAMINER	
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/594,839

Applicant(s)

ANTHONY ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-46 and 48-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicants' response to the office action filed on May 26, 2004 has been entered.
2. The instant application is filed on June 15, 2000, which claims no priority date.
3. Claims 1-55 are pending. Non-elected claim 47 is withdrawn from consideration.

**Response to arguments**

4. Applicants' response to the office action is fully considered and found persuasive.
5. With reference to the rejection made in the previous office action under 35 USC 112 second paragraph, Applicants' amendment and arguments are fully considered and the rejection is withdrawn herein in view of the amendment.
6. With reference to the rejection made in the previous office action under 35 USC 102(b), Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment and arguments and new grounds of rejection.
7. With reference to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment arguments and new grounds of rejection.

***New Grounds of Rejections***

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-46, 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Impraim et al. (USPN. 6,228,578) in view of Nathan et al. (USPN. 6,057,099) and Shah et al. (USPN. 5,629,156).

Impraim et al teach a method of claims 1, 22, 37-38, and 40, 46, of detecting a target nucleic acid comprising:

(a) hybridizing a target nucleic acid sample with probes (which include a mixture of HPV 6 and HPV 11 probes which are considered as capture and signal probes, biotinylated or enzyme labeled) hybridizing to said target nucleic acid at different regions (non-overlapping regions) to a to form a double-stranded hybrids (see column 6, line 34-40, col. 7, line 5-10);

(b) adding a blocker to the hybridization reaction, where in said blocker hybridizes to excess non-hybridized probe sequences (see column 9, line 20-50);

(c) capturing the sequence probe:target hybrid to form a bound hybrid (see col. 7, line 14-22);

(d) detecting the bound hybrid (see column 9, line 51-67).

With regard to claims 3, 5, 24-26, 43-44, Impraim et al. teach that the capture probe is modified with a biotin ligand (see col. 6, line 43-47);

With regard to claims 11, 30, Impraim et al teach that the method comprises forming single stranded DNA (denature DNA) prior to hybridization (see co. 17, lines 25-29);

With regard to claim 14, 39, Impraim et al. teach that the blocker probe has lower melting temperature than that of capture sequence probe (see col. 9, line 20-37);

With regard to claim 15-18, 23, 32-35, 41, Impraim et al. teach immobilization of probe-target hybrid to streptavidin coated tubes or microtiter plates (see col. 7, line 47-67, col. 8, line 1-39);

With regard to claims 10, 19-20, 21, 22, 36, 42, Impraim et al. also teach that detection of bound hybrid using antibody wherein the hybrid is labeled with alkaline phosphatase enzyme (see col. 8, line 42-67, col. 10, line 26-36) and the is RNA-DNA hybrid (see column 7, line 13-22). However, Impraim et al. did not teach blocker probe, immobilization of the probes and use of bridge probes or dT-tailed probes.

Natan et al teach a method of detecting a target nucleic acid comprising:

(a) hybridizing a target nucleic acid sample (DNA or RNA) (see column 2, lines 56-57) to a capture sequence probe (first oligonucleotide) and a signal sequence probe (second oligonucleotide probe) to form a double-stranded hybrids between said probes and the target nucleic acid, (b) adding a blocker to the hybridization reaction, where in said blocker hybridizes to excess non-hybridized capture probe sequences or signal probe sequences (see column 5, lines 31-63, column 21, lines 7-24). Natan et al. also teach that the method comprises formation of RNA-DNA hybrid (see column 6, lines 20-23).

Shah et al. teach a method of detecting a target nucleic acid wherein Shah et al. disclose that the method comprises hybridizing a target nucleic acid (DNA or RNA) to a capture probe and a detector probe (signal probe), and detecting the bound hybrid (see column 7, lines 17-29, column 3, lines 60-67, column 4, lines 1-51, and column 6, lines 30-57). Shah et al. also teaches immobilization of capture probe on to a solid support (see column 4, lines 29-32); The capture or release using first and second capture probes can be performed in either order (simultaneously or sequentially) (see column 6, lines 58-65). Further Shah et al. teach use of dA-tailed probes (bridge probes) which bind to both target and dT derivitized supports such that the binding is stronger to the targets than the supports (see column 8, lines 44-54); capture probes biotinylated at both ends (column 9, lines 58-67); the capture probe and the detector probe distance when hybridized to a target comprises less than 3.0kb (see column 9. lines 31-57, see base pair distance of SEQ ID nos.1-4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting a target nucleic acid as taught by Impraim et al. with the step of adding blocker probes or oligonucleotides as taught by Nathan et al. and dT-tailed probes and immobilization of capture probes as taught by Shah et al. to achieve expected benefit of developing an enhanced and improved method for detecting a nucleic acid because Nathan et al. taught that use of blocker oligonucleotides reduces background signal (see col. 5, line 31-63) and Shah et al. taught that 'the new assay format eliminates noise due to nonspecific binding of the detector probe to the capture probe and can produce a sandwich hybridization assay entirely free of background noise (see col. 3, line 49-64). In order to reduce signal to noise ratio in hybridization assays involving DNA-RNA interaction, an ordinary

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practitioner would have been motivated to modify the method of detecting a target nucleic acid as taught by Imprain et al. by incorporating the steps of adding blocker oligonucleotides, immobilizing the capture probes and using dT-tailed probes as taught by Nathan et al. and Shah et al., to develop a method that would improve sensitivity and specificity of detecting a target nucleic acid which would result in reduced background signal noise and enhanced sensitivity and specificity of the detection method.


### ***Conclusion***


No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
September 15, 2004

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

9/20/04